



## **SCIENCE AND TECHNOLOGY POLICY OFFICE**

### **Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology**

**AGENCY:** National Science and Technology Council.

**ACTION:** Notice of Request for Information,

**SUMMARY:** On July 2, 2015, the Executive Office of the President (EOP) issued a memorandum (Ref. 1) directing the primary agencies that regulate the products of biotechnology—the U.S. Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA)—to update the Coordinated Framework for the Regulation of Biotechnology (51 FR 23302; June 26, 1986) (Ref. 2), develop a long-term strategy to ensure that the Federal biotechnology regulatory system is prepared for the future products of biotechnology, and commission an expert analysis of the future landscape of biotechnology products to support this effort. The memorandum's objectives are to ensure public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products while continuing to protect health and the environment.

The purpose of this Request for Information (RFI) is to solicit relevant data and information, including case studies, that can assist in the development of the proposed update to the Coordinated Framework for the Regulation of Biotechnology (CF) to clarify the current roles

and responsibilities of the EPA, FDA, and USDA and the development of a long-term strategy consistent with the objectives described in the July 2, 2015 EOP memorandum. In addition to this RFI, the update to the CF will undergo public comment before it is finalized.

**DATES:** Responses must be received by November 13, 2015 at 5:00 PM EST to be considered.

**ADDRESSES:** You may submit information by either of the following methods (electronic is strongly preferred):

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Docket No. FDA-2015-N-3403. Follow the instructions for submitting information. Information submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged.
- *Mail:* National Science and Technology Council: Emerging Technologies Interagency Policy Coordination Committee, Office of Science and Technology Policy, 1650 Pennsylvania Avenue NW, Washington, DC 20504. If submitting a response by mail, please allow sufficient time for mail processing. Written/paper information, including attachments, will be posted to the docket unchanged.

*Instructions:* All submissions received must include Docket No. FDA-2015-N-3403 for Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology; Request for Information.

*Disclaimer:* All information received will be placed in the docket and will be publicly viewable at <http://www.regulations.gov>. Responses must be unclassified and should not contain

any information that might be considered proprietary, confidential, or personally identifying (such as home address or social security number).

Responses to this RFI will not be returned. The National Science and Technology Council is under no obligation to acknowledge receipt of the information received, or provide feedback to respondents with respect to any information submitted under this RFI. No requests for a bid package or solicitation will be accepted; no bid package or solicitation exists. This RFI is issued solely for information and planning purposes and does not constitute a solicitation.

**FOR FURTHER INFORMATION CONTACT:** National Science and Technology Council: Emerging Technologies Interagency Policy Coordination Committee, Office of Science and Technology Policy, Executive Office of the President, Eisenhower Executive Office Building, 1650 Pennsylvania Ave., Washington DC 20504, Phone: 202-456-4444, Online: <https://www.whitehouse.gov/webform/contact-emerging-technologies-interagency-policy-coordinating-committee-national-science-and>

## **SUPPLEMENTARY INFORMATION:**

### **Background Information**

In 1986, the Office of Science and Technology Policy (OSTP) issued the Coordinated Framework for the Regulation of Biotechnology (CF), which outlined a comprehensive Federal regulatory policy for ensuring the safety of biotechnology products. The CF sought to achieve a balance between regulation adequate to ensure the protection of health and the environment while maintaining sufficient regulatory flexibility to avoid impeding innovation.

In 1992, OSTP issued an update to the CF that sets forth a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment (57 FR 6753; February 27, 1992) (Ref. 3). The update affirmed that Federal oversight should

focus on the characteristics of the product, the environment into which it is being introduced, and the intended use of the product, rather than the process by which the product is created.

On July 2, 2015 the Executive Office of the President (EOP) issued a memorandum directing the primary Federal agencies that have oversight responsibilities for the products of biotechnology—the U.S. Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA)—to update the CF to clarify the current roles and responsibilities of the agencies that regulate the products of biotechnology, develop a long-term strategy to ensure that the Federal biotechnology regulatory system is prepared for the future products of biotechnology, and commission an independent, expert analysis of the future landscape of biotechnology products. These efforts will build on the regulatory principles described in the CF and the 1992 update to the CF. The memorandum's objectives are to ensure public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products while continuing to protect health and the environment.

The July 2, 2015 EOP memorandum stated that the update to the CF should clarify the current roles and responsibilities of the agencies that regulate the products of biotechnology by accomplishing the following four objectives:

- (i) clarifying which biotechnology product areas are within the authority and responsibility of each agency;
- (ii) clarifying the roles that each agency plays for different product areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment;

- (iii) clarifying a standard mechanism for communication and, as appropriate, coordination among agencies, while they perform their respective regulatory functions, and for identifying agency designees responsible for this coordination function; and
- (iv) clarifying the mechanism and timeline for regularly reviewing, and updating as appropriate, the CF to minimize delays, support innovation, protect health and the environment and promote the public trust in the regulatory systems for biotechnology products.

As noted in the July 2, 2015 EOP memorandum, “biotechnology products” refers to products developed through genetic engineering or the targeted or in vitro manipulation of genetic information of organisms, including plants, animals, and microbes. It also covers some of the products produced by such plants, animals, and microbes or their derived products as determined by existing statutes and regulations. Products such as human drugs and medical devices are not the focus of the activities described in the memorandum.

The purpose of this RFI is to solicit relevant data and information, including case studies, that can inform the development of the proposed update to the CF and the development of a long-term strategy consistent with the objectives described in the July 2, 2015 EOP memorandum. In addition to this RFI, the update to the CF will undergo public comment before it is finalized.

## **Information Requested**

The National Science and Technology Council requests relevant data and information, including case studies, that can inform the update to the CF by clarifying the current roles and responsibilities of the EPA, FDA, and USDA and the development of the long-term strategy consistent with the objectives described in the July 2, 2015 EOP memorandum. For details on the current roles and responsibilities of these agencies, refer to their websites.

### Relevant FDA Websites

- <http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/>
- <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113605.htm>

### Relevant EPA Websites

- <http://www.epa.gov/pesticides/biopesticides/regtools/biotech-reg-prod.htm>
- [http://www.epa.gov/biotech\\_rule/](http://www.epa.gov/biotech_rule/)

### Relevant USDA Websites

- <https://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology>

A brief summary of these agencies' current roles follows.

The FDA regulates products of genetically engineered (GE) organisms that fall within FDA's authority under the Federal Food, Drug, and Cosmetic (FD&C) Act and other statutes. The FDA is responsible for ensuring the safety of all plant-derived human and animal foods, including those that are from genetically engineered sources. FDA also regulates GE animals under the new animal drug provisions of the FD&C Act, and FDA's regulations for new animal

drugs. (The actual regulated article is the recombinant DNA construct inserted into a specific site in the genome of an animal; as a shorthand, the FDA refers to the regulation of GE animals.)

Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for protecting agriculture from pests and diseases. Under the Plant Protection Act (PPA) and the Animal Health Protection Act (AHPA), USDA-APHIS has regulatory oversight over products of modern biotechnology that could pose a risk to plant and animal health. The AHPA provides authority to prohibit or restrict imports or entry into the United States or dissemination of any pest or disease of livestock. GE animals and insects would be subject to import or transport restrictions if there is a risk to animal health. The PPA, as amended, provides authority to regulate the introduction (i.e., importation, interstate movement, or release into the environment) of certain GE organisms and products. A GE organism is considered a regulated article if the donor organism, recipient organism, vector, or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation and is also considered a plant pest. A GE organism is also regulated when APHIS has reason to believe that the GE organism may be a plant pest. A GE organism is no longer subject to the plant pest provisions of the PPA or to regulatory requirements when APHIS determines that it is unlikely to pose a plant pest risk.

The EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the FD&C Act regulates the sale and distribution of all pesticides, including those produced through genetic engineering. This includes microorganisms, biochemicals isolated from organisms, and plant-incorporated protectants (PIPs), a type of pesticide intended to be produced and used in living plants. Under the Toxic Substances Control Act (TSCA), EPA has oversight responsibilities for a wide range of commercial, industrial, and consumer applications of

microbial biotechnology. New chemicals produced through those microbial biotechnology applications are subject to premanufacturing review under TSCA.

## **Questions**

Keeping in mind the principles of the regulation of the products of biotechnology as articulated in the CF and the 1992 update to the CF, as well as the objectives of the July 2, 2015 EOP memorandum, respondents are welcome to address one or more of the following questions in regards to the proposed update to the CF and the development of the long-term strategy. Respondents are asked to indicate to which question responses are targeted.



1. What additional clarification could be provided regarding which biotechnology product areas are within the statutory authority and responsibility of each agency?
2. What additional clarification could be provided regarding the roles that each agency plays for different biotechnology product areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment?
3. How can Federal agencies improve their communication to consumers, industry, and other stakeholders regarding the authorities, practices, and bases for decision-making used to ensure the safety of the products of biotechnology?
4. Are there relevant data and information, including case studies, that can inform the update to the CF or the development of the long-term strategy regarding how to improve the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology?
5. Are there specific issues that should be addressed in the update of the CF or in the long-term strategy in order to increase the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology?

## References

These references are available electronically at <http://www.regulations.gov>. We have verified the Web site addresses, but we are not responsible for any subsequent changes to Web sites after this document publishes in the Federal Register.

1. Executive Office of the President. Office of Science and Technology Policy, Office of Management and Budget, United States Trade Representative, and Council on Environmental Quality. Modernizing the Regulatory System for Biotechnology Products, July 2, 2015. Available online at:

[https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing\\_the\\_reg\\_system\\_for\\_biotech\\_products\\_memo\\_final.pdf](https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf).

2. Executive Office of the President. Office of Science and Technology Policy. Coordinated Framework for Regulation of Biotechnology. 51 FR 23302, June 26, 1986. Available online at: [http://www.aphis.usda.gov/brs/fedregister/coordinated\\_framework.pdf](http://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf)
3. Executive Office of the President. Office of Science and Technology Policy. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment. 57 FR 6753, February 27, 1992. Available online at: [https://www.whitehouse.gov/sites/default/files/microsites/ostp/57\\_fed\\_reg\\_6753\\_1992.pdf](https://www.whitehouse.gov/sites/default/files/microsites/ostp/57_fed_reg_6753_1992.pdf)

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Ted Wackler, Deputy Chief of Staff and Assistant Director.

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